Roll No. | | | | | | | | | | | | | Total No. of Pages : 02

Total No. of Questions : 10

B.Pharma (2011 to 2016) (Sem.–8)

PHARMACEUTICS-IX (DOSAGE FORM DESIGN)

Subject Code : BPHM-801

Time : 3 Hrs. Max. Marks : 80

INSTRUCTIONS TO CANDIDATES :

1. **SECTION-A is COMPULSORY consisting of FIFTEEN questions carrying TWO marks each.**
2. **SECTION-B contains FIVE questions carrying FIVE marks each and students have to attempt any FOUR questions.**
3. **SECTION-C contains FOUR questions carrying TEN marks each and students have to attempt any THREE questions.**

SECTION-A

1. Answer briefly :

a) What is meant by pharmaceutic equivalent?

b) What is retrospective validation?

c) What is racemization? Give two examples.

d) Give two examples of BCS III drugs.

e) What should be the disintegration time of dispersible tablets IP?

f) Mention the stability testing conditions for Zone II.

g) Propyl gallate and EDTA are used for which purposes?

h) Give examples of two drugs that are formulated in micronized state.

i) Mention the methods that can be used for enhancing the solubility of poorly water soluble drugs.

j) Differentiate between controlled and delayed release.

k) Why is DOSS added to dissolution media?

l) What is absolute availability?

m) What is the difference between excretion and elimination?

n) Enumerate different types of particle diameters.

o) What is meant by sedimentation volume of suspensions?

SECTION-B

2. Write briefly about the impact of particle size and shape in influencing the stability of suspensions.

3. Giving examples of prodrugs that have proven advantage over their parent molecular forms, explain the reasons thereof.

4. What is BCS? Briefly describe the different classes of drugs giving examples.

5. Give examples of drugs that are highly prone to oxidation and suggest methods to make them stable.

6. Write a brief note on Quality Audit.

SECTION-C

7. Enlist the physicochemical properties of drugs that are evaluated during preformulation phase. Discuss the importance of particle size, shape and density in influencing dosage form development.

8. What is validation? Explain the different types of validations and mention the conditions for which they are carried out.

9. Discuss the key features of a Bioequivalence trial. Discuss the ICH requirements for establishing Bioequivalence of drug products.

10. Discuss the IVIVC requirements according to ICH guidelines.

NOTE : Disclosure of Identity by writing Mobile No. or Making of passing request on any page of Answer Sheet will lead to UMC against the Student.